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Original Article

Grades of Intrinsic Sphincteric Deficiency (ISD) Associated with Female Stress Urinary Incontinence

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Abstract: Intrinsic urethral sphincter deficiency (ISD) is a clinical entity that should be suspected in women with stress urinary incontinence. If it is not diagnosed prior to surgery, it poses a significant risk factor for repair failure. We propose a classification of ISD based on videofluorourodynamic (VFUD) and abdominal leak-point pressures. One hundred female patients with stress urinary incontinence due to ISD were included in this study. History and physical examination were performed on all patients. Each patient underwent a standard VFUD study with abdominal leak-point pressure (ALPP) measurement. ISD is classified into subtypes according to VFUDS and ALPP. The findings were then correlated with the clinical presentation, etiology and proposed management. Three types of ISD/SUI were identified. ISD-A, subtle/urodynamic, was present in 32 patients (32%). It is most difficult to diagnose because radiologically the bladder neck is not open at rest, and it is only diagnosed by VFUD. The abdominal leak-point pressure was less than 12 cmH_2O. ISD-B was present in 45 patients (45%). This is characterized by a beak-shaped open bladder neck at rest. The abdominal leak-point pressure was less than 90 cmH_2O. ISD-C was present in 14 patients (14%). It is characterized by an open, fixed non-functioning urethra (pipe-stem) with high position of the bladder neck. The abdominal leak-point pressure was less than 70 cmH_2O. All the three subtypes had proximal urethral closure pressure (PCUP) less than 10 cmH_2O. Based on these data, the treatment options may vary from one subtype to another. For ISD-A, initial treatment was medical, with collagen injection being used for the failed cases. For ISD-B a modified pubovaginal sling was used, as it corrects the ISD and the urethral hypermobility at the same time. For ISD-C, urethrolysis and takedown of the previous suspension was required before using a sling. Collagen injections were used in selected cases. This classification identifies different subgroups of ISD, which is important in the diagnosis and management of this condition.

Keywords: Classification; Intrinsic sphincter deficiency; Leak-point pressures; Stress urinary incontinence; Videourodynamics

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Introduction

Stress urinary incontinence (SUI) is a major social problem affecting 10%–35% of the almost 30 million Americans over the age of 65 [1]. The precise anatomical and physiological mechanisms involved in the maintenance of urinary continence are poorly understood. A well-supported bladder neck and proximal urethra with a good functioning intrinsic urethral sphincter are the primary factors responsible for continence [2,3]. Distal (external) urethral sphincter integrity is also vital for maintaining continence. Stress urinary incontinence may occur mainly by two mechanisms. The first, and the most common, is weak support of the bladder neck, which leads to hypermobility and significant posterior rotational displacement secondary to loss of the 'hammock effect' [4]. Types I and II are different degrees of displacement of the bladder neck [5,6]. The other cause of SUI is intrinsic sphincter deficiency (ISD), defined by McGuire as type III in

females [7]. In ISD there is extremely poor or no proximal urethral closure pressure (PUCP) (<10 cmH_2O) [7].

There are combinations of physiologic characteristics that maintain continence under abdominal stress conditions. These may include viscoelastic properties, integrity of periurethral striated muscle function, optimal neurologic innervation, urethral vascularity, mucosal seal, urethral striated muscle integrity, and as yet unquantified factors. Damage to these desirable factors may be caused by pelvic surgery, radical hysterectomy, anterior bowel resection, severe denervation/reinnervation of the pelvic floor secondary to obstetric delivery and trauma, previous failed incontinence surgery, urethral surgery for diverticula, and neurological conditions affecting the sacral roots. Indeed, ISD may be caused by one or several factors. Currently no single urodynamic measurement exists that can diagnose ISD on its own.

The purposes of a classification system for stress incontinence are to facilitate understanding of the etiology and pathophysiology and to allow the use of this information to establish treatment guidelines. Moreover, further characterization of ISD in females will provide comparison between the rapidly changing treatment modalities and outcomes.

Patients and Methods

A retrospective analysis was performed of 100 consecutive women with a clinical and videofluorourodynamic (VFUD) diagnosis of stress urinary incontinence secondary to ISD. Most of the patients had been referred by urologists or gynecologists for VFUD studies. For each patient, a detailed history, voiding diary and physical examination in the dorsal lithotomy position with a full bladder were performed. If incontinence was not demonstrated with cough or Valsalva maneuver, the patient was re-examined in the sitting or standing position. Also, for each patient a standard VFUD study using a 10 Fr triple-lumen urodynamic catheter (BARD) was performed by Life-tech machine (Urovision, Houston, TX). Iodinated contrast material (30% Hypaque) was infused at 50 ml/min at room temperature. Vesical and urethral pressures were recorded by perfusion of the apertures at 1 ml/min from a constant-pressure reservoir connected to an interchangeable-pressure transducer (Life-tech, Urovision, Houston, TX) with a frequency response of 0.2 s/100 cmH_2O. A balloon catheter was placed in the rectum. Urodynamic parameters were mixed with the video image in real time and the whole process was fluoroscopically guided and videotaped for later review and documentation.

After 100 ml had been infused – enough to visualize the bladder neck – the catheter was manually withdrawn under fluoroscopic control to measure the urethral pressure profile (UPP). The marker of the urethral port was positioned 1–1.5 cm distal to the bladder neck under fluoroscopic guidance to measure proximal urethral pressure. The proximal closure urethral pressure (PCUP) was calculated as the difference between P_{ura} and P_{ves}. At 150 ml, abdominal leak-point pressure (ALPP) was determined by asking the patient to increase abdominal pressure by straining (Valsalva maneuver). If no leakage was seen, the patient was asked to cough three times in a row. If no leakage was again seen, this step was repeated at 300 ml (supine and standing). Also, the anatomical changes in the bladder, urethra (urethral hypermobility) and pelvic floor were evaluated during resting, coughing, bearing down, and voiding in the oblique position. The process was repeated in the standing position. At full capacity, a voiding study was performed [9–12]. In the presence of a large cystocele, a vaginal pack test was used in which a gauze pack was inserted into the vagina to unmask the effect of cystocele [13].

Because most of the patients were referrals, it was only possible to analyze treatment data for 38 patients who received treatment at Tulane University Medical Center.

All the definitions are in accordance with the International Continence Society (ICS) recommendations unless otherwise mentioned [14]. The statistical program used was InStat II (InStat statistics program, GraphPad, San Diego, CA, USA). P values of <0.05 were considered statistically significant.

Results

The ages of the 100 patients ranged from 12 to 82 years (mean 60.1 $\pm$ 13.8). A total of 140 previous pelvic surgeries or anti-incontinence procedures were found in 76 patients. Most of the previous pelvic surgeries were hysterectomies, either transvaginal or transabdominal, with or without a concomitant anti-incontinence procedure (usually anterior repair with Kelly's plication, Marshall–Marchetti–Krantz or Burch colposuspension) performed at the same time. The presenting symptoms are shown in Table 1.

Accordingly, the patients with ISD were classified into three subtypes (Table 2).

Table 1. Demographics and symptoms of 100 consecutive patients with ISD incontinence

	ISD-A†	ISD-B†	ISD-C†
No. of patients (%)	32 (32)	54 (54)	14 (14)
Age (years)*	61.7 ± 14.4	60.2 ± 12.7	56.3 ± 17
Parity*	2.8 ± 1.4	2.6 ± 1.5	2.6 ± 1.3
Urge incontinence*	13 (40.6%)	28 (51.8%)	10 (71.4%)
Duration (years)*	4.8 ± 4.0	7 ± 6.2	10 ± 7.9
Frequency*	5.4 ± 1.9	5.8 ± 2.9	7.5 ± 2.3
Nocturia*	2 ± 1.4	2 ± 1.4	3 ± 1.8
Pads*	2.6 ± 2	3.3 ± 2	5.7 ± 2.7
Pelvic procedures†	36 (1.1)	69 (1.3)	35 (2.5)

* Values expressed as mean $\pm$ SD.
† Pelvic and anti-incontinence procedures expressed as total and (average per patient).

Table 2. Classification of ISD

ISD-A	Subtle/urodynamic (Fig. 1); loss of functional urethral closure, common in elderly females; urethral hypermobility is common; only diagnosed by VFUDS
ISD-B	Beak-shaped open bladder neck (Fig. 2); may show mild degree of mobility with stress
ISD-C	Pipe-stem urethra (Fig. 3) fixed in position; severe incontinence; suggestive history (e.g. pelvic surgery or radiation etc.)

1. **ISD-A** (subtle/uroynamic; Fig. 1) is the most difficult type to diagnose because radiographically the bladder neck is not open at rest, and it is only diagnosed by VFUDS (i.e. low PCUP and open bladder neck with stress). In addition, there is often urethral hypermobility that could mask the underlying ISD.
2. **ISD-B** (beak-shaped; Fig. 2) is characterized by a high-positioned and beak-shaped bladder neck, because of the presence of contrast material in the proximal area of the bladder neck. It may be accompanied by mild hypermobility with stress. In this case the bladder neck will be beak-shaped but in a low position.

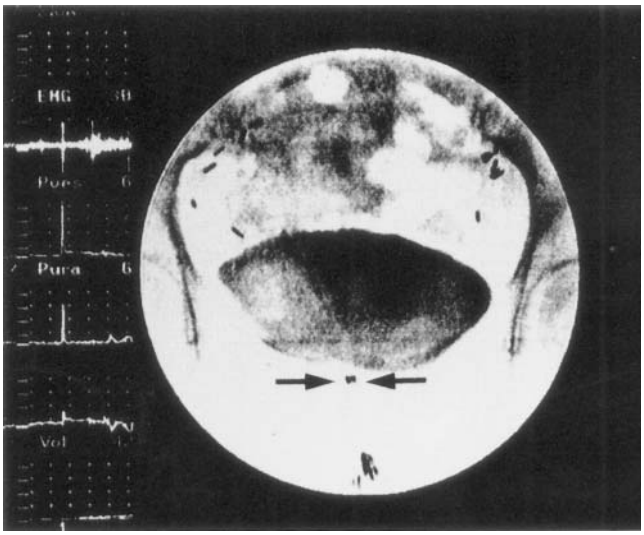

Fig. 1. ISD-A (subtle/urodynamic).

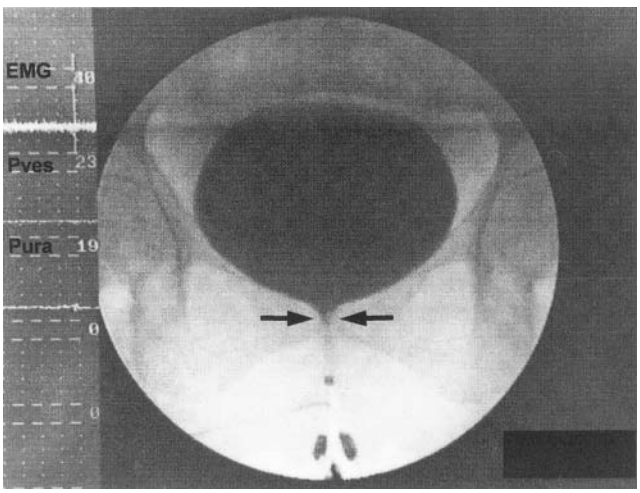

Fig. 2. ISD-B (beak-shaped).

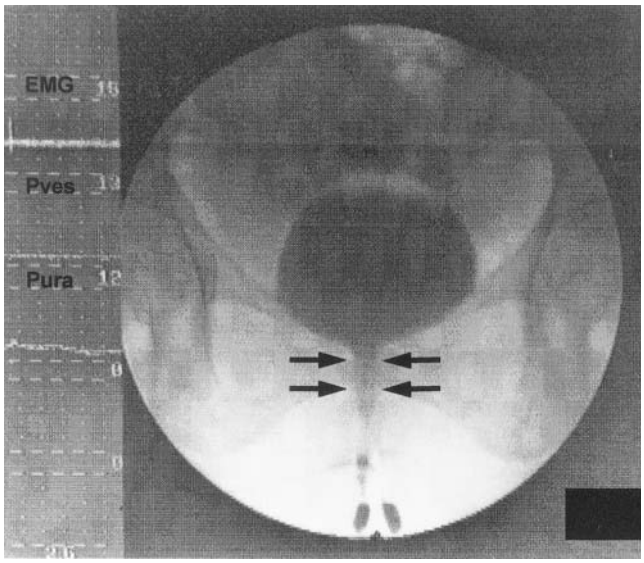

Fig. 3. ISD-C (pipe stem).

3. **ISD-C** (pipe-stem; Fig. 3) is characterized by an open, fixed, non-functioning urethra (pipe-stem) with a high position of the bladder neck. This type is usually encountered in patients with previous irradiation or a history of multiple pelvic surgeries. Also, it is seen in female patients with long-standing urethral catheter drainage.

ISD-A incontinence was found in 32 patients (32%), ISD-B in 54 (54%) and ISD-C in 14 (14%). Urgency and/or urge incontinence was found in 13 patients (40.6%) with ISD-A, in 28 (51.8%) with ISD-B, and in 10 (71.4%) with ISD-C. Also, similar observations were found among the groups concerning nocturia, number of pads used, and previous pelvic or anti-incontinence procedures (Table 1).

The urodynamic data are presented in Table 3. In patients with ISD-A the bladder neck was closed at rest but had a low proximal urethral closure pressure (<10 cmH_2O). When the patient was asked to cough, the bladder neck opened and contrast appeared in the urethra. Because the bladder neck was *not* visualized by fluoroscopy, the diagnosis was only made by VFUD (subtle/urodynamic). For ISD-B the characteristic picture was the beak-shaped open bladder neck. Both ISD-A and ISD-B were associated in some cases with pelvic floor lesions. Cystocele was found in 9 cases (28%) in the ISD-A group and in 19 patients (35%) with ISD-B. Also, urethral hypermobility was found in 20 patients (62%) with ISD-A, and in 28 patients (51.8%) with ISD-B. However, pelvic relaxation was minimal in ISD-A patients. In ISD-C the urethra was

Table 3. Videofluorourodynamic data (VFUD)

	ISD-A**	ISD-B**	ISD-C**	*p*-value
Residual urine (ml)	7.8 ± 17.9	16.6 ± 23.2	18.2 ± 25.8	ns
Bladder capacity (ml)	379.7 ± 62.8	391.7 ± 77.7	321.4 ± 66.4	ISD-A#ISD-C* ISD-B#ISD-C*
PUP (cmH_2O)	12.4 ± 7.2	9.1 ± 6.0	5.9 ± 4.2	ISD-A#ISD-C*
PCUP (cmH_2O)	8.8 ± 8.1	4.3 ± 4.1	2.6 ± 3.6	ISD-A#ISD-B* ISD-A#ISD-C*
MUP (cmH_2O)	42.6 ± 19.4	36.3 ± 13.9	37.1 ± 17.4	ns
Supine ALPP (cmH_2O)	112.8 ± 40.9	75.1 ± 33.0	64 ± 21.6	ISD-A#ISD-B* ISD-A#ISD-C*
Standing ALPP (cmH_2O)	120.3 ± 40.7	80.1 ± 44.1	63 ± 52.7	ISD-A#ISD-B* ISD-A#ISD-C*:
Fluoroscopy of outlet	Closed bladder neck	Beak-shaped	Pipe-stem	
Ureth. hypermobility†	20 (62%)	28 (51.8%)	2 (14.2%)	
Cystocele/rectocele†	9 (28%)	19 (35%)	1 (7.1%)	

PUP, proximal urethral pressure; PCUP, proximal closure urethral pressure; MUP, maximal urethral pressure; ALPP, abdominal leak-point pressure.
† Parmeters are expressed as number of patients (%).
** The urodynamic parameters are expressed as mean ± SD.
* $P<0.05$ (ANOVA).

widely open and fixed (pipe-stem urethra). This type was rarely associated with urethral hypermobility or pelvic prolapse. For other urodynamic parameters there was a significant change of values of PCUP and SLP between different groups. The values for ISD-A were higher than those of both ISD-B and ISD-C. No significant change was found concerning postvoid residual urine volume or maximal urethral pressure between groups (Table 3).

As Tulane University Medical Center is a tertiary referral institution, many patients come for VFUD evaluation only. Only 38 out of 100 patients were treated at this center. Based on these data, the treatment lines varied from one subtype to another. For ISD-A, medical treatment in the form of conjugated estrogen cream (Premarin, Wyeth-Ayerst Laboratories, Philadelphia, PA) with or without α-adrenergic stimulant containing phenylpropanolamine (Ornade, Smithkline Beecham, Pittsburgh, PA) was used in a dose of 75 mg b.i.d. If this failed or was contraindicated, a collagen injection was used (Contigen, C.R. Bard, Covington, GA). For ISD-A, 11 patients were treated by α-adrenergic stimulant ± conjugated estrogen cream, Kegel's exercises and/or electrical stimulation. The follow-up was 6 months. All patients tolerated the therapy well and all of them improved. A modified pubovaginal sling (MPVS) [8] was performed in 4 cases because of associated cystocele and urethral hypermobility. However, 1 patient received α-adrenergic stimulant for 4 months, until she underwent a hysterectomy for uterine fibroids and a concurrent modified pubovaginal sling. Collagen injection was performed, with excellent results, in 2 cases.

For ISD-B a sling procedure was used, particularly if there was urethral hypermobility. A modified pubovaginal sling (MPVS) was placed in 10 patients, and collagen injection was used in another 4 (refused surgery or old age).

For ISD-C, urethrolysis and takedown of the previous suspension were required before positioning the rectus fascial sling. Also, collagen injections were used in selected cases. The overall success rate (Table 4) was 94.7% (2 case failures: one sling, and one collagen).

MPVS with cystourethrolysis was performed in 7 cases. One of them developed obstruction and needed sling release with vaginal patch interposition [15]. Also, 1 case of collagen injection failed because of marked urethral fibrosis, and needed a sling procedure.

Table 4. Classification at a glance

	ISD-A	ISD-B	ISD-C
Stress test	+ve	+ve	+ve
PUCP	<10	<10	<10
Bladder neck on VFUD	Closed at rest, open with stress	Beaked shaped, open at rest	Pipe stem, open at rest
ALPP	<120	<90	<70
Primary treatment	Medical/behavioral	Injection therapy	Injection therapy
Secondary treatment	Injection therapy	Suburethral sling	Urethrolysis, takedown of previous sling and suburethral sling

Discussion

No standardized terminology or definition exists for ISD. In 1907, Giordano [15] recognized that the urinary incontinence is caused by a loss of the internal sphincter mechanism. Since then, many surgeons have tried to define ISD, but no significant measurement was found to be enough for diagnosis. McGuire used fluorourodynamic techniques to define cases of SUI, using a low proximal urethral closure pressure of $\leqslant 10$ cmH_2O as type III SUI. In these studies, he reported about a 30% prevalence of ISD in 875 patients with SUI [6,16,17], and warned that a low maximum urethral pressure per se does not establish the diagnosis of ISD: a compromised internal sphincteric function should be demonstrated, as well as low proximal urethral pressure. Low-pressure urethra is a term defining by an MUCP, (maximum urethral closure pressure) $\leqslant 20$ cmH_2O; this term is usually used by urogynecologists, and conceivably overlaps in many cases with ISD diagnosed by VFUDS and ALPP. Usually, fluorourodynamic studies are needed. Horbach and Ostergard reported a prevalence rate of ISD of 50.2% of cases of SUI [18]. In their study, ISD was diagnosed when the MUCP was 20 cmH_2O or less. Richardson et al. reported an 11% incidence of ISD in patients with SUI [19]. These differences may be due to the different techniques used to assess urethral pressure, to the referral-based population and, most importantly, using different criteria for diagnosis of ISD in each study. However, low-pressure urethra cannot be taken as a sole indicator for ISD. There is a great overlap between the urethral pressures of continent and incontinence women. Furthermore, patients with low-pressure urethra have been treated successfully with standard retropubic urethropexy, indicating the absence of associated ISD [19].

Another confusing issue in the diagnosis of ISD is the presence of an open bladder neck. Blaivas and Olsson reported an ISD rate of 21% in 181 patients with SUI [20]. The criteria for diagnosis were a radiologically open bladder neck and low sphincteric pressure. Cystoscopy and physical examination significantly highlight the presence of ISD. In the previously mentioned study by Horbach and Ostergard, they reported an open bladder neck, diagnosed endoscopically, in only 2.3% of patients, and stated that these patients could be easily recognized from the history of high-grade incontinence without urodynamic measurement. Therefore, they concluded that the majority of patients with a poorly functioning urethra might be missed if the diagnosis was based only on endoscopy with an open bladder neck [18]. Open bladder neck may or may not produce stress urinary incontinence, depending on the compensatory mechanisms. Versi et al. [21] studied 147 women presenting to an incontinence clinic and noted that the prevalence of open bladder neck at rest was 21%. The correlation with an incompetent sphincter was 0.613 (probability of sphincteric incompetence with resultant incontinence). In another study, Versi and Cardozo demonstrated radiologically that 50% of normal climacteric continent women may have an incompetent bladder neck at coughing. They postulated that these women, at the time of coughing, maintain continence because of the integrity of the external sphincter [22]. So, incompetence of the bladder neck should not be used as the sole parameter for a diagnosis of ISD as a cause of urinary incontinence.

McGuire introduced the abdominal leak-point pressure (ALPP) as a diagnostic tool for evaluating incontinent patients. This method is simple and depends on dynamic evaluation of the overall bladder outlet resistance to abdominal stress. Suggested values over 90 cmH_2O are characteristic of urethral hypermobility. A value of $\leqslant 60$ cmH_2O is characteristic of ISD. Values between 60 and 90 cmH_2O may be due to urethral hypermobility or ISD [23]. Although these values are not based on critical studies, they correlate well with VFUD findings in most patients. Swift and Ostergard reported that the abdominal leak-point pressure has poor clinical correlation to the maximal urethral closure pressure, but they stated that the abdominal leak-point pressure of <60 cmH_2O is 90% sensitive and 64% specific in detecting a low-pressure urethra [24]. A better approach to diagnosing ISD depends on a combination of history, physical examination, Q-tip test and urodynamic testing, without sole reliance on any one parameter [25].

Using sophisticated VFUD in this study, patients were diagnosed to have SUI and ISD. The dysfunction of the internal sphincter varied in severity from the mild form of ISD-A to the severe form of ISD-C. So, the described technique helped to clarify a subtle type of ISD (ISD-A) and also ISD-B. Also, it clarifies the possible association of urethral hypermobility with any subtype of ISD.

ISD-A represented 32% of the patients and was characterized by relatively high abdominal leak-point pressures (112.8 ± 40.9). This type presented in relatively older patients with fewer previous operations (1.1/patient) and more urethral hypermobility. Also the number of pads was small, along with mild associated symptoms such as frequency, urgency and urge incontinence. The low proximal urethral pressure can be attributed to the old age of the patients, with possible loss of elasticity and vascularity of the internal sphincter. Because compensatory mechanisms, such as a normally functioning external sphincter, are intact, a relatively high ALPP could be expected. In this group, the patients who have associated urethral hypermobility will benefit most from a suburethral sling operation. However, those with pure ISD-A can be treated with less morbid and less invasive techniques. These may include medical treatment with local vaginal estrogen cream, with or without α-adrenergic oral therapy. Kegel exercises, biofeedback or electrical stimulation may also have a role.

Some of these patients with ISD-A benefit from conservative therapy, as shown in this study of good results with a 6-month follow-up. The incontinence grade improved but none became totally dry as expected. Most of these patients preferred to stay on conservative treatment rather than undergo a surgical procedure. In

failed cases, collagen was injected or a sling was performed, particularly if another pathology was present, such as urethral hypermobility with cystocele or rectocele.

ISD-B was found in the majority of patients (54%). This type was easily diagnosed, being characterized by an open beak-shaped bladder neck and urethral hypermobility (50% of cases). The SLP was less than in ISD-A because of the marked hypermobility in addition to the open bladder neck. So, for this type the sling procedure was ideal, as urethral support and coaptation were maintained at the same time. Collagen injection was done only in patients who were elderly or who refused surgery, or in cases not associated with pelvic prolapse or urethral hypermobility.

ISD-C was present in 14% of cases. This type was characterized by high-grade incontinence, the use of more pads, many previous pelvic surgeries (2.5 per patient) and a long duration of incontinence. On VFUD it was easily diagnosed by a widely open fixed urethra. Also, both ALPP and urethral closure pressure were low. This type represents the severe form of ISD and is probably the only type where all of the different diagnostic modalities agree. History, physical examination, Q-tip test, low-pressure urethra, low ALPP, ISD by VFUD and cystoscopy are positive. For this type, a bulking agent may be given by injection, but the failure rate may be high because the extensive fibrosis could cause difficulty in implantation of the collagen. Alternatively, a sling operation can be carried out. Extensive urethrolysis is an essential component of the sling procedure. We present an algorithm suggesting a management approach (Fig. 4),

VFUD plays an important role in detecting and quantifying the presence of ISD. This includes cases where the diagnosis was initially missed and patients presented with recurrence of stress incontinence, especially after a Burch colposuspension or needle suspension. Additionally, VFUD should be performed in patients with previous pelvic surgery, which contributes multifactorially to the development of ISD. In this study we were able to demonstrate a combination of features suggestive of ISD in groups subtyped as A and B which would have been missed if VFUD had not been performed. The estimation of PUCP is best done under fluoroscopic visualization of the bladder neck. Further, the procedure also clearly demonstrated the passage of dye into the proximal urethra. Some would disagree that the minimal passage of dye on stress and the 'eagle-beaking' sign are evidence of urethral sphincter incompetence. However, all the patients in our study had undergone at least one previous pelvic surgical procedure (group A = 1.1, group B = 1.3, group C = 2.5), and hence were clearly at risk for ISD. We feel that such a constellation of features is suggestive of ISD in a high-risk population.

In conclusion, this functional classification (Table 4) clarifies different distinct groups of ISD, identifies important etiological and pathophysiological factors, aids in diagnosis and possibly management of this condition, and serves as a model for further research into ISD, including proximal urethral pressure compliance, hormonal influences and other conditions.

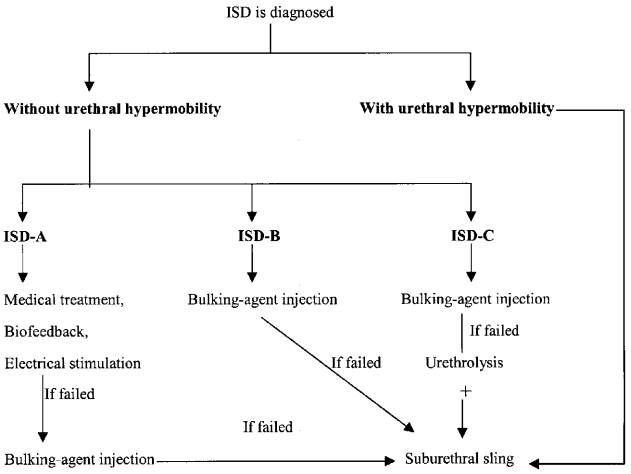

Fig. 4. Suggested algorithm for the treatment of ISD.

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EDITORIAL COMMENT: The authors carefully examined urodynamic data derived from the evaluation of a large group of women with genuine stress incontinence. The precise criteria for the identification of the condition of intrinsic sphincter deficiency are not given, but included leak-point pressure testing and videourodynamics with identification of a poorly functional proximal urethra. The authors attempt to differentiate the videourodynamic diagnosis of intrinsic sphincter deficiency from the diagnosis of what has been previously termed a low-pressure urethra. The claim is that the distal sphincter is where the urethra pressure is generated, and so this test measures the function of this portion of the urethra. They ultimately classified patients into different groups and recommended, via an algorithm, different modalities of therapy based on their diagnostic criteria. The study is a step in the right direction in an attempt to objectify and quantify various degrees of stress incontinence. However, more objective follow-up results of the algorithm would be required prior to incorporating it into one's clinical practice.